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INTERNA	ATIONAL APPLICATION NO. PCT/EP00/05801	INTERNATIONAL FILING DATE 23 June 2000	PRIORITY DATE CLAIMED 28 June 1999			
TITLE O	F INVENTION METHOD AND I	DEVICE FOR PRODUCING PELLETS				
	•	ng Joerg; Johann Schwartz; Andreas Ege				
Applicant	herewith submits to the United Sta	ates Designated/Elected Office (DO/EO/US)	the following items and other information:			
I. 🔽 TI	his is a FIRST submission of items	s concerning a filing under 35 U.S.C. 371.				
2. T1	his is a SECOND or SUBSEQUEN	IT submission of items concerning a filing u	mder 35 U.S.C. 371.			
3. 🔽 TI	nis is an express request to begin n	ational examination procedures (35 U.S.C. 3	71(f)). The submission must include			
	ems (5), (6), (9) and (21) indicated the US has been elected by the expi	below. ration of 19 months from the priority date (A	article 31).			
	copy of the International Applicat		21).			
a.	is attached hereto (required	d only if not communicated by the Internation	nal Bureau).			
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		he International Application as filed (35 U.S	.C. 371(c)(2)).			
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21. The follow	ing fees are submitted:			CAI	CULATIONS 1	PTO USE ONLY
BASIC NATIONAL	FEE (37 CFR 1.492 (a)					
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Serial No. : to be assigned) Art Unit: Confirmation No.: to be assigned) Examiner:

I.A. Filing Date : June 23, 2000 : December 19, 2001 Submitted

For : Method and Device for Producing Pellets

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Assistant Commissioner for Patents

Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Please cancel Claims 1 through 14.

Please add the following new claims, 15 through 29 as shown on the enclosed pages.

Respectfully submitted,

Mary Ellen M. Devlin Attorney for Applicant(s)

Reg. No. 27,928

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Ridgefield, CT 06877 Tel.: (203) 798-4866 Docket No. 5/1263

ASSISTANT

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PATENTS.

raugh Mary-Ellen M. Devlin Reg. No. 23,928



- 15. A Process for producing pellets (4) from a viscous medium (2), wherein the medium (2) to be processed is fed continuously to a metering device (11, 61) which is operated under cyclical control, by means of which the medium (2) is divided into individual fragments (3) of a pre-selected length and these fragments are expelled or ejected over a pre-selected distance (S).
- 16. The process as recited in Claim 15 wherein the medium is fed continuously under constant pressure.
- 17. The process according to claim 15, wherein the temperature of the medium (2) to be processed is adjusted, before it is fed to the metering device (11, 61), by heating or cooling a storage container (5, 54) or a delivery line (6) or the metering device (11, 61), or a combination of one or more of the foregoing.
- 18. The process according to claim 15, wherein the temperature of the expelled fragments (3) is controlled during the ejection over the entire area or in one or more parts of the distance (S).

- 19. The process according to claim 15, wherein the individual fragments (3) are expelled at an accelerated speed, e.g. with the aid of a discharge device (21).
- 20. The process according to claim 15, wherein the fragments (3) are provided with a coating during the ejection.
- The process according to claim 15, wherein the fragments (3) are expelled in a ballistic trajectory.
- 22. An apparatus (1, 61) for producing pellets (4) from a viscous medium (2), which comprises a metering device (11, 61) operated under cyclical control, to which the medium (2) to be processed is supplied continuously under pressure and by means of which the medium (2) is divided into individual fragments (3) of a pre-selected length which are preferably expelled at an accelerated rate over a pre-selected travel distance (S).
- 23. The apparatus according to claim 22, wherein the metering device (11) is constructed as a shutoff valve (12) which can be operated cyclically by magnetic, hydraulic, pneumatic, piezoelectric or mechanical means.

- 24. The apparatus according to claim 23, wherein the valve member of the shutoff valve (12) may be constructed as a sphere (14) or cone (15) co-operating with a spherically shaped valve surface (16) or as a slide member (17) which can be pushed into the delivery line (6) and is provided with a tip (18) which is triangular in cross section.
 - 25. The apparatus according to claim 22, wherein the metering device (11) may be constructed as a fluidic valve constructed in the form of a section of hose (19) attached to the delivery line (6) and provided with a piezo-actuated drive element.
 - 26. The apparatus according to claim 22, wherein the metering device (61) is formed as a valve tappet (62) displaceably inserted in a housing (52) and operated cyclically by magnetic, hydraulic, pneumatic, piezoelectric or mechanical means, which has a spherically or conically shaped tip (63) and cooperates with a collecting chamber (65) to which the medium (2) may be fed from a storage container (54) preferably integrated in the housing (52).
 - 27. The apparatus according to claim 26, wherein valve tappet (62) has associated therewith a conically shaped

chamber (57) adapted to fit the tip (63) thereof, having an outlet port (958) adjoining the latter.

- 28. The apparatus according to claim 22, wherein a discharge device (21) is provided downstream of the metering device (11).
- 29. The apparatus according to claim 28, wherein adjoining the discharge device (21) is an oscillator (40) in which a vibration of 20 Hz to 20 kHz is produced by means of a generator (41).

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Method and Device for Producing Pellets

The invention relates to a process for producing pellets from a viscous medium and an apparatus for carrying out this process.

In drug therapy, pellets are frequently used as carriers for pharmaceutical substances; they are prepared by various methods, some of which are very laborious.

According to one of these methods, the so-called spray hardening method, a liquid medium enriched with the pharmaceutical substances is continuously forced through a spray nozzle. On leaving the spray nozzle, the jet of liquid is broken up into particles of different sizes which harden as they fall.

Uniform pellets, i.e. those of identical size, which have reproducible and predictable release characteristics, cannot be produced by this method, however, but instead the particles obtained in a broad spectrum of sizes have to be sorted by screening in a subsequent operation. Apart from the fact that sometimes a large proportion of the medium being processed has to be rejected, in order to produce pellets of other sizes it is necessary to change the nozzle and subsequently grade the pellets. The work involved in manufacture, even with this simple spray hardening process, is therefore considerable.

The aim of the invention is therefore to provide a process for producing pellets from a viscous medium and an apparatus for carrying out this process which make it possible always to produce uniform pellets of virtually the same size and reproducibility, which will therefore have the same release characteristics, in a single operation.

Moreover, it should be possible to vary the size of the pellets by simple means and to process media of differing viscosity. The labour involved in achieving this should be kept to a minimum but at the same time the pellets should be capable of being produced cheaply within a short space of time.

According to the invention, the process by which this is to be achieved is characterised in that the medium which is to be processed is supplied continuously, under preferably constant pressure, to a metering device which can be operated cyclically, by means of which the medium is divided into individual fragments of a given length and these are ejected over a pre-selected distance.

It is useful to adjust the temperature of the medium being processed before it is fed into the metering device by heating or cooling a storage container and/or a delivery line and/or the metering device and to adjust the temperature of the ejected fragments during the ejection over the entire area or in one or more sections of a distance by means of the ambient temperature. The individual fragments can also be ejected at high speed by means of a discharge device, in which the fragments are expelled in a ballistic trajectory and can be provided with a coating during the ejection.

The apparatus for carrying out this process is characterised by a metering device which can be operated cyclically, to which the medium to be processed can be supplied continuously under pressure and by means of which the medium can be divided up into individual fragments of a given size which can preferably be ejected at high speed and over a pre-selected distance.

The metering device may be constructed as a shutoff valve which is operated cyclically by magnetic, hydraulic, pneumatic, piezoelectronic or mechanical means, while the valve member of the shutoff valve may be constructed as a sphere or cone co-operating with a spherically shaped valve surface or as a slide which can be pushed into the delivery line, provided with a tip which is triangular in cross section.

However, the metering device may also be constructed as a fluidic valve constructed in the form of a section of hose attached to the delivery line and provided with a piezo-actuated drive element.

According to another embodiment, the metering device may also be constructed as a valve tappet which is displaceably inserted in a housing and is cyclically operated by magnetic, hydraulic, pneumatic, piezo-electronic

or mechanical means, which has a conical or spherical tip and co-operates with a collecting chamber to which the medium can be fed from a storage container preferably integrated in the housing.

It is appropriate to associate with the valve tappet a conically shaped chamber adapted to fit its tip and to incorporate the chamber as well as an outlet port adjoining said chamber in a cover which is releasably connected to the housing.

In order to ensure a uniform supply of the medium which is to be processed, the collecting chamber is to be formed by two or more supply channels extending radially to the chamber associated with the valve tappet, preferably incorporated in the cover, these channels being connected to the storage container directly via an annular space or via connecting channels.

Moreover, the storage container and/or the housing should be fitted with heating cartridges in the region of the collecting chamber and in order to drive the valve tappet a piston should be provided which is mounted in a guide bushing replaceably inserted in the housing.

It is also advantageous to provide, downstream of the metering device, a discharge device which can be supplied with a carrier medium, e.g. compressed air, to accelerate the fragments which are to be expelled.

Experience has shown that there is a possibility of the discharge device becoming blocked. To counter the risk of

blockage, an oscillator may advantageously be included in the apparatus. This oscillator is directly connected to the discharge device and generates a vibration of 20 Hz to 20 kHz, depending on the type of fouling which is transferred to the discharge device. This vibration is produced in the oscillator by means of a generator. As a result of this oscillating effect, no medium for processing is left on the opening and the product drips off cleanly.

The outlet port of the metering device or of the discharge device should be inclined upward at an angle \forall of 25 to 35° to the horizontal, in order to achieve a ballistic trajectory.

It is also advisable to provide, downstream of the metering device or the discharge device, a tunnel equipped with cooling elements and/or having a gas atmosphere, which is supposed to have an operating pressure below or above atmospheric pressure and which may be fitted with one or more spray nozzles for coating the fragments or pellets. In addition, a catching container may be provided downstream of the metering device or the discharge device.

Moreover, the medium which is to be processed should be enclosed in a heatable or coolable storage container. The metering device, preferably together with the drive members and optionally the discharge device, may be arranged together in one housing.

Using the process according to the invention or the apparatus for carrying out this process, it is extremely

easy and cheap to produce pellets of virtually identical size and hence with constant reproducibility, as carriers of pharmaceutical substances, from a viscous medium and to change their size without any difficulty, if required.

Using the metering device, in fact, the medium which is continuously supplied under pressure can be divided into individual fragments the length of which can be adjusted to suit the intended use, and these fragments can be ejected at high speed so that the fragments are shaped into pellets during their flight as a result of the surface tension present, these pellets taking on the same shape as one another, since the fragments supplied have the same shape and the conditions of ejection of the fragments are also the same. There is therefore no need to grade them; nor is there any reject material.

Since all the pellets produced in one step of the process therefore have virtually the same shape and surface, the release characteristics of the particular group of pellets will be reproducibly uniform and predictable.

Moreover, during manufacture, the size of the pellets produced can readily be controlled using the metering apparatus, since the metering apparatus can easily be made to open and close cyclically and individual sizes of pellet can readily be produced by varying the opening and closing times. Thus, by connecting a plurality of control mechanisms with correspondingly high cycle rates in parallel, pharmaceutical formulations can be produced

extremely economically by manufacturing pellets with a homogeneous particle profile.

The drawings show two embodiments of an apparatus constructed according to the invention for producing pellets from a viscous medium, which will be described more fully hereinafter. In the drawings, which are diagrammatic:

Figure 1 shows a block circuit diagram of an apparatus provided with a metering device,

Figure 2 shows the apparatus of Figure 1 with a discharge device connected downstream,

Figure 3 shows the apparatus of Figure 1 in a modified $\ensuremath{\mathsf{e}}$ embodiment.

Figure 4 shows the metering device of the apparatus according to Figure 3 on a larger scale,

Figures 5 and 6 show different embodiments of the metering device which may be used in the apparatus of Figure 1.

Figure 7 shows a tunnel which may be used in the apparatus of Figure 1,

Figure 8 shows a different embodiment of an apparatus for producing pellets, in axial section,

Figure 9 shows the apparatus according to Figure 8, in side elevation,

Figure 10 shows a detail of Figure 8 on a larger scale and

Figure 11 shows the metering device according to Figure 4 but with an oscillator which prevents blockage of the discharge device.

The apparatus shown in Figures 1 to 3 and 8 and 9 and designated 1 and 51 is used to produce pellets 4 of identical shape from a viscous material 2 which is stored in a storage container 5 in the apparatus 1 and fed continuously, under pressure, through a delivery line 6 equipped with a pump 7. In order to convert the flow of medium 2 into the pellets 4, the apparatus 1 is provided with a metering device 11 in which the medium 4 is divided into individual fragments 3 of equal length from which the fragments 3 are ejected into a catching container 10 over a given distance S. The metering device 11 is disposed in a housing 8.

In the apparatus 1 according to Figure 1 the metering device 11 is formed by a shutoff valve 12 which can be operated electrically, hydraulically, pneumatically, piezoelectrically or mechanically by means of a drive member 13. The shutoff valve 12 may be formed, as shown in Figures 4, 5 and 6, by a ball 14 or by a cone 15, as shown by a dotted line in Figure 4, as a movable valve member which cooperates with a spherically shaped valve seat 16, or by a slide member 17 engaging with its conical tip 18 in the delivery line 6.

According to Figure 6, the metering device is constructed as a fluidic member in the form of a hose section 19 connected to the delivery line 6 and surrounded by a piezo-actuated drive element 20. The medium 2 is again divided into fragments by the pressure acting on the hose section 19 from outside.

According to Figure 2, downstream of the metering device 11 is a discharge device 21 which is connected to the metering device 11 via an intermediate line 9. By means of the discharge device 11 the fragments 3 are ejected at high speed. To achieve this, a carrier medium, e.g. compressed air, is supplied to the discharge device 21 through a line 22 and acts on the fragments 3 which are to be ejected.

According to Figure 11, downstream of the metering device 11 is a discharge device 21 which is connected to the metering device 11 via an intermediate line 9. The oscillator 40 is connected directly to the discharge device 21. The generator 41 sets the oscillator 40 vibrating. This oscillating system helps prevent blockage of the nozzle.

Downstream of the discharge device 21, according to Figure 7, is a tunnel 31 in which the expelled fragments 3 can be cooled down by means of a gas atmosphere 35. In addition, the tunnel 31 may be fitted with spray nozzles 36 by means of which an active substance 37 can be sprayed, for example, in order to coat the fragments 3 and/or pellets 4.

As shown in Figure 3, the storage container 5 may optionally be fitted with heating elements 32 to increase the viscosity of the medium 2 stored therein. For the same purpose, the metering device 11 may be kept at a constant operating temperature by means of heating elements 33.

There are also cooling elements 34 in the tunnel 31 according to Figure 3, for cooling the pellets 4.

The pellets 4 are produced by means of the apparatus 1 as follows: the medium 2 which is continuously fed into the metering device 11 by means of the pump 7 at a constant pressure is divided into individual fragments 3 by the shutoff valve 12 which opens and closes cyclically; by varying the opening and closing times of the shutoff valve 12 the length of the fragments 3 can be adjusted individually.

Closing the shutoff valve 12 causes the valve member to accelerate the fragments 3 additionally and eject them faster, directly or by means of the discharge device 21. In their flight over the distance S adjacent to this discharge device 21 the individual fragments 3 are deformed as a result of surface tension, as shown in Figure 7, to form spherical pellets 4 which are virtually identical in size and reproducibility.

In the apparatus 51 for producing pellets shown in Figures 8 to 10, the metering device 61 is formed by a valve tappet 62 provided with a conically shaped tip 63 which cooperates with a suitably shaped chamber 57. The valve

tappet 62 is movably inserted in a housing 52 which contains a storage container 54 for the medium which is to be processed and guide channels 55 and 55' through which the medium can be fed via an annular space 66 into a collecting chamber 65 associated with the valve tappet 62.

In the embodiment shown, the collecting chamber 65 is formed by three radially directed channels 67 which are connected to the annular space 66 and open into the chamber 57 which is bounded by a counter-surface 59 associated with the valve tappet 62.

The channels 67 and also the chamber 57 are incorporated in a cover screwed onto the housing 52. Also, an outlet port 58 through which the fragments can be expelled individually is provided in the cover on an extension of the chamber 57.

The valve tappet 62 is driven by a cyclically operated piston 64 which is displaceably mounted in a bushing 53 inserted in the housing 52. Its passage through the housing 52 is sealed off by a membrane 68 through which the valve tappet 62 passes. Also, in order that the medium can be processed at any selected operating temperature, a plurality of heating cartridges 69 or 70 are inserted in the housing 52 in the region of the storage container 54 and valve tappet 62.

The medium located in the storage container 54 is acted upon by pressurised gas via a connection 60, so that the medium is forced through the channels 55, 55', the annular

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space 66 and the channels 67 forming the collecting chamber 65 into the chamber 57. If the valve tappet 62 is driven cyclically by means of the piston 64, at each stroke a fragment corresponding to the capacity of the chamber 57 is forced out of the discharge port 58 and is then automatically shaped into a pellet.

Patent Claims

- Process for producing pellets (4) from a viscous medium (2), characterised in that the medium (2) to be processed is fed continuously, under preferably constant pressure, to a metering device (11, 61) which is operated under cyclical control, by means of which the medium (2) is divided into individual fragments (3) of a pre-selected length and these fragments are expelled or ejected over a pre-selected distance (S).
- Process according to claim 1, characterised in that the temperature of the medium (2) to be processed is adjusted, before it is fed to the metering device (11, 61), by heating or cooling a storage container (5, 54) and/or a delivery line (6) and/or the metering device (11, 61).
- 3. Process according to claim 1 or 2, characterised in that the temperature of the expelled fragments (3) is controlled during the ejection over the entire area or in one or more parts of the distance (S), preferably by means of the ambient temperature.
- Process according to one or more of claims 1 to 3, characterised in that the individual fragments (3) are

expelled at an accelerated speed, e.g. with the aid of a discharge device (21).

- 5. Process according to one or more of claims 1 to 4, characterised in that the fragments (3) are provided with a coating during the ejection.
- 6. Process according to one of more of claims 1 to 5, characterised in that the fragments (3) are expelled in a ballistic trajectory.
- 7. Apparatus (1, 61) for producing pellets (4) from a viscous medium (2), characterised by a metering device (11, 61) operated under cyclical control, to which the medium (2) to be processed is supplied continuously under pressure and by means of which the medium (2) is divided into individual fragments (3) of a pre-selected length which are preferably expelled at an accelerated rate over a pre-selected travel distance (S).
- 8. Apparatus according to claim 7, characterised in that the metering device (11) is constructed as a shutoff valve (12) which can be operated cyclically by magnetic, hydraulic, pneumatic, piezoelectric or mechanical means.

- 9. Apparatus according to claim 8, characterised in that the valve member of the shutoff valve (12) may be constructed as a sphere (14) or cone (15) co-operating with a spherically shaped valve surface (16) or as a slide member (17) which can be pushed into the delivery line (6) and is provided with a tip (18) which is triangular in cross section.
- 10. Apparatus according to claim 7, characterised in that the metering device (11) may be constructed as a fluidic valve constructed in the form of a section of hose (19) attached to the delivery line (6) and provided with a piezo-actuated drive element.
- 11. Apparatus according to claim 7, characterised in that the metering device (61) is formed as a valve tappet (62) displaceably inserted in a housing (52) and operated cyclically by magnetic, hydraulic, pneumatic, piezoelectric or mechanical means, which has a spherically or conically shaped tip (63) and cooperates with a collecting chamber (65) to which the medium (2) may be fed from a storage container (54) preferably integrated in the housing (52).
- 12. Apparatus according to claim 11, characterised in that associated with the valve tappet (62) is a conically shaped chamber (57) adapted to fit the tip (63)

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thereof, having an outlet port (958) adjoining the latter.

- 13. Apparatus according to one or more of claims 7 to 12, characterised in that a discharge device (21) is provided downstream of the metering device (11).
- 14. Apparatus according to claim 13, characterised in that adjoining the discharge device 21 is an oscillator 40 in which a vibration of 20 Hz to 20 kHz is produced by means of a generator 41.

10/018641

Abstract

In an apparatus (1) for producing pellets (4) from a viscous medium (2), a metering device (11) which is operated under cyclical control is provided, to which the medium (2) to be processed is fed continuously under pressure and by means of which the medium (2) is divisible into individual fragments (3) of pre-selected length which are ejected over

By means of the apparatus (1), pellets (4) of virtually identical size intended as carriers for pharmaceutical substances can be produced with constant reproducibility (Figure 3).

Fig. 1

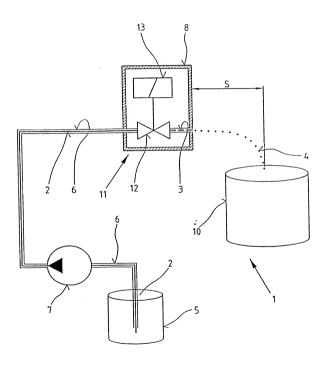


Fig. 2

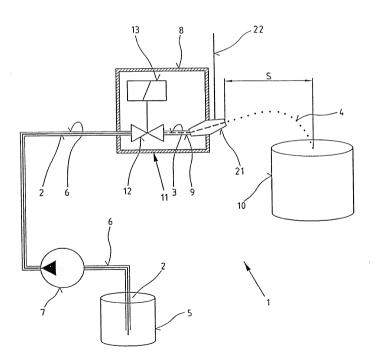
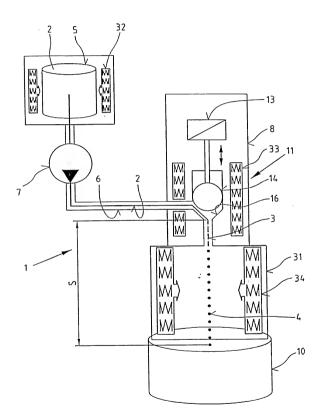
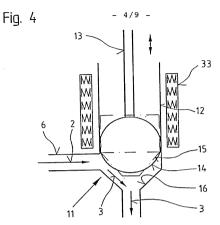


Fig. 3



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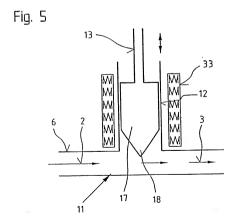


Fig. 6

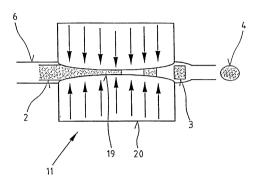
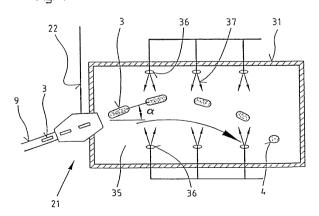
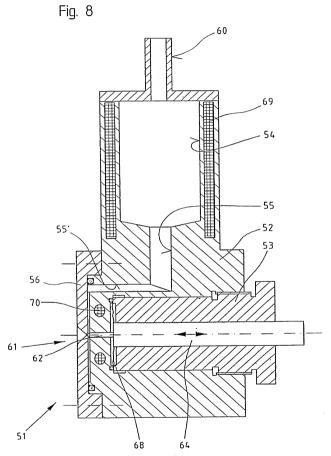


Fig. 7







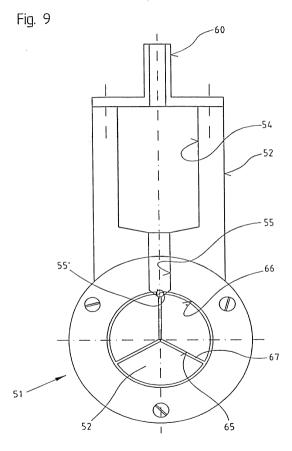


Fig. 10

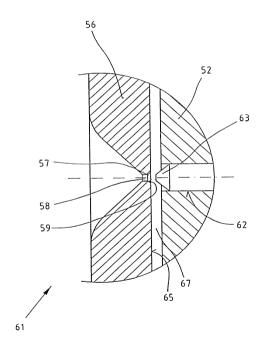
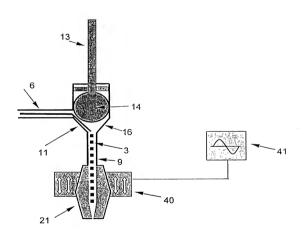


Fig. 11



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U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. 5/1263 PCT Attorney Docket Number DECLARATION FOR UTILITY OR Wolfgang Joerg et al. First Named Inventor DESIGN COMPLETE IF KNOWN PATENT APPLICATION (37 CFR 1.63) Application Number 018.641 Filing Date December 19, 2001 Declaration Declaration Submitted after Initial Submitted OR Art Unit To be assigned Filing (surcharge (37 CFR 1.16 (e)) with Initial Filing To be assigned required) Evaminer Name As the below named inventor, I hereby declare that: My residence, mailing address, and citizenship are as stated below next to my name. I believe I am the original and first inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled: Method and Devise for Producing Pellets (Title of the Invention) the specification of which is attached hereto 06/23/2000 was filed on (MM/DD/YYYY) as United States Application Number or PCT International PCT/EP00/05801 12/19/2001 and was amended on (MM/DD/YYYY) (if applicable). Application Number I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above. I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the ordinual or PCT international filing date of the ordinualion-in-part application. international multipolitic of the Controlled Controlled Property of the Con claimed Foreign Filing Date Priority Certified Copy Attached? Prior Foreign Application Number(s) Country (MM/DD/YYYY) Not Claimed NO YES 199 29 526.3 Germany 06/28/1999 PCT/EP00/05801 06/23/2000 Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto-

[Page 1 of 2]

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Additional inventors are being named on the _1__supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto. [Page 2 of 2]

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Inventor's Andrew Ex						Date 04/02 /2002
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City Mittelbiberach	State		ZIP 8	B441	Coun	try Germany
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Robert		E	Becker			1
Inventor's Signature	_					Date 04 02 20
Residence: City Biberach	State Z	100	Country	Germ	any	Citizenship DE
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Mailing Address						
Biberach City	State		ZIP	88400	Co	Germany
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Residence: City Baltringen	State D	EX	Country	Gern	nany	Citizenship
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10/018.641 Application Number December 19, 2001 Filing Date Wolfgang Joerg et al. First Named Inventor Method and Devise for Producing Pellets Title To be assigned **Group Art Unit** To be assigned Examiner Name 5/1263 PCT Attorney Docket Number

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		First Named Inventor	Wolfgang Joerg et al.
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